Public Health Service

BIOLOGICAL MATERIALS LICENSE AGREEMENT

This Agreement is entered into between the Public Health Service ("PHS"), through the Office of Technology Transfer, National Institutes of Health, Box OTT, Bethesda, MD 20892, USA, and "LICENSEE"), a corporation of _____ having an office at

_____.

1. Definitions:

a. “Materials" means the following biological materials including all progeny, subclones, and derivatives thereof:
_____ as described in

_____ and developed in the laboratory of _____.

b. "Licensed Products" means_____.

c. "Net Sales" means the total gross receipts by LICENSEE for sales of Licensed Products, or for income from leasing, renting or otherwise making Licensed Products available to others without sale or other disposition transferring title, whether invoiced or not, less returns and allowances actually granted, packing costs, insurance costs, freight out, taxes or excise duties imposed on the transaction (if separately invoiced), and wholesaler and cash discounts in amounts customary in the trade. No deductions shall be made for commissions paid to individuals, whether they be with independent sales agencies or regularly employed by LICENSEE, or for the cost of collections.

2. LICENSEE wishes to obtain a license from PHS to use the Materials provided under this Agreement in its commercial research or product development and marketing activities. LICENSEE represents that it has the facilities, personnel and expertise to use the Materials for commercial purposes and agrees to expend reasonable efforts and resources to develop the Materials for commercial use and/or commercial research.

3. PHS hereby grants to LICENSEE a worldwide, non-exclusive license to make, have made and use the Materials and to make, have made, use and sell Licensed Products in the field of use of:

4. PHS agrees to provide LICENSEE with samples of the Materials, excluding progeny, subclones and derivatives thereof, ("Supplied Materials"), as available, and at reasonable cost to replace the Supplied Materials, as available, in the event of their unintentional destruction.

5. In consideration of the grant in Paragraph 3 above, LICENSEE hereby agrees to make the following payments to PHS:

> a. Within 30 days of its execution of this Agreement, a noncreditable, nonrefundable license issue royalty of _____ Dollars ($_____).
>
> b. A nonrefundable minimum annual royalty of _____ Dollars ($_____) which shall be due and payable on January 1 of each calendar and may be credited against earned royalties for due for sales made in that year. The minimum annual royalty for the first calendar year of this Agreement is due and payable within thirty (30) days from the effective date of this Agreement

and may be prorated according to the fraction of the calendar year remaining between the effective date of this Agreement and the next subsequent January 1.

c. An earned royalty of _____ percent (___%) of Net Sales, which shall be due and payable within sixty days of the end of each calendar year. All payments required under this Agreement shall be in US Dollars, net of all non-US taxes, and shall be made by check or bank draft drawn on a United States bank and made payable to "NIH/Patent Licensing." All such payments shall be sent to the following address: NIH, PO Box 360120, Pittsburgh, PA 15251- 6120.

6. LICENSEE agrees to make written reports to PHS within sixty (60) days after the end of each calendar year. This report shall state the number, description, and aggregate Net Sales of Licensed Products made, sold, or otherwise disposed of, and the total gross income received by LICENSEE from leasing, renting, or otherwise making Licensed Products available to others without sale or other disposition transferring title, during such completed calendar year, and resulting calculation pursuant to Paragraph 5 of payment due.

LICENSEE shall submit each such report along with payment due PHS for the calendar year covered by the report to PHS at the address listed in Paragraph 5 above and shall also send a copy of the report to PHS at the Mailing Address for Notices indicated on the Signature Page of this Agreement. Late charges will be applied to any overdue payments as required by the US Department of Treasury in the Treasury Fiscal Requirements Manual, Section 8025.40. The payment of such late charges shall not prevent PHS from exercising any other rights it may have as a consequence of the lateness of any payment.

7. LICENSEE agrees to supply the laboratory of Dr. _____ (PHS) at no charge reasonable quantities of Materials and Licensed Products that LICENSEE offers for sale or otherwise makes available for public use.

8. This Agreement shall become effective on the date when the last party to sign has executed this Agreement and shall terminate _____(____) years from this effective date, unless previously terminated under the terms of Paragraphs 16 or 17 below.

9. As part of LICENSEE's performance under this Agreement, LICENSEE agrees to:

_____

_____

_____.

10. LICENSEE agrees to retain control over the Materials, and not to distribute them to third parties without the prior written consent of PHS except as provided in Paragraph 3.

11. LICENSEE agrees that this Agreement does not preclude PHS from distributing the Materials to third parties for research or commercial purposes.

12. By this Agreement, PHS grants no patent rights expressly or by implication to any anticipated or pending PHS patent applications or issued patents.

13. NO WARRANTIES, EXPRESS OR IMPLIED, ARE OFFERED AS TO THE MERCHANTABILITY OR FITNESS FOR ANY PURPOSE OF THE MATERIALS PROVIDED TO LICENSEE UNDER THIS AGREEMENT, OR THAT THE MATERIALS OR LICENSED PRODUCTS MAY BE EXPLOITED WITHOUT INFRINGING THE PATENT RIGHTS OF ANY THIRD PARTIES. LICENSEE accepts license rights to the Materials and Licensed Products "as is", and PHS does not offer any guarantee of any kind.

14. LICENSEE agrees to indemnify and hold harmless the United States government from any claims, costs, damages or losses that may arise from or through LICENSEE's use of the Materials or Licensed Products. LICENSEE further agrees that it will not by its action bring the United States government into any lawsuit involving the Materials or Licensed Products.

15. LICENSEE agrees in its use of any PHS-supplied materials to comply with all applicable statutes, regulations and guidelines, including Public Health Service and PHS regulations and guidelines. LICENSEE agrees not to use the Materials for research involving human subjects or clinical trials in the United States without complying with 21 CFR Part 50 and 45 CFR Part 46. LICENSEE agrees not to use the Materials for research involving human subjects or clinical trials outside of the United States without notifying PHS, in writing, of such research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to PHS of research involving human subjects or clinical trials outside of the United States shall be given no later than sixty (60) days prior to commencement of such research or trials.

16. LICENSEE may terminate this Agreement upon sixty (60) days written notice to PHS.

17. PHS may terminate this Agreement if LICENSEE is in default in the performance of any material obligation under this Agreement, and if the default has not been remedied within ninety (90) days after the date of written notice by PHS of such default.

18. Upon termination of this Agreement, LICENSEE agrees to return all Materials and Licensed Products to PHS, or provide PHS with certification of their destruction.

19. Within ninety (90) days of termination of this Agreement, LICENSEE agrees to submit a final report to PHS, and to submit payment of any royalties due.

20. LICENSEE is encouraged to publish the results of its research projects using the Materials or Licensed Products. In all oral presentations or written publications concerning the Materials or Licensed Products, LICENSEE will acknowledge the contribution of Dr. _____and the PHS agency supplying the Materials, unless requested otherwise by PHS or Dr. _____.

21. This Agreement shall be construed in accordance with the laws of the United States as interpreted and applied by the Federal courts in the District of Columbia.

22. This Agreement constitutes the entire understanding of PHS and LICENSEE and supersedes all prior agreements and understandings with respect to the Materials.

23. The provisions of this Agreement are severable, and in the event that any provision of this Agreement shall be determined to be invalid or unenforceable under any controlling body of law, such invalidity or unenforceability shall not in any way affect the validity or enforceability of the remaining provisions of this Agreement.

24. Paragraphs 9, 13, 14, and 20 of this Agreement shall survive termination of this Agreement.

SIGNATURE PAGE

In Witness Whereof, the parties have executed this agreement on the dates set forth below. Any communication or notice to be given shall be forwarded to the respective addresses listed below.

FOR PHS:

_____(Signature) Date: _____
Barbara McGarey, JD
Deputy Director
Office of Technology Transfer
National Institutes of Health

Mailing Address for Notices: Office of Technology Transfer, National Institutes of Health, Box OTT, Bethesda, MD 20892

FOR LICENSEE:

(Upon information and belief, the undersigned expressly certifies or affirms that the contents of any statements of LICENSEE made or referred to in this Agreement are truthful and accurate.)

Signature: _____ Date:_____

Printed Name _____

Title _____

Mailing Address for Notices:
_____
_____
_____